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CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 07/29/2003 HM-101 10/629,527 Harry Moulis 6056 EXAMINER 12/28/2004 7590 Van Dyke & Associates, P.A. VIRDI, SUNDEEP Suite 252 PAPER NUMBER ART UNIT 7200 Lake Ellenor Drive Orlando, FL 32809 3763

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | · A | pplication No. | Applicant(s) | |
|--|--|-----|---|-----------------------------------|--|
| Office Action Summary | | 1 | 0/629,527 | MOULIS, HARRY | |
| | | E | xaminer | Art Unit | |
| | | | undeep S Virdi | 3763 | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1)⊠ Res | Responsive to communication(s) filed on 29 July 2003. | | | | |
| 2a)☐ This | This action is FINAL . 2b)⊠ This action is non-final. | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) 1-17 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-17 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) ☐ The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 29 July 2003 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) | | | | | |
| 1) Notice of R | 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | | | Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other: | te atent Application (PTO-152) | |

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaskell (4,023,559).

Gaskell discloses a cannulated catheter (20) comprising an elongated portion (1), said elongated portion comprising a proximate end (1a) and a distal end (1b), with a retractable device (2) that is extended and retracted out the distal end of the catheter and a squeezable material (11) disposed within the retractable device.

With regard to claim2, Gaskell discloses the retractable device connected to a mechanical interlink (10).

3. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Wallach (6,387,058).

Wallach discloses a cannulated catheter comprising an elongated portion (30) with a proximate and distal end (see figure 1) with a retractable device that is extended and retracted out the distal end of the catheter (see figure 1), the device comprising a brush (11) that comprises at least one lumen (14) in fluid communication with said cannulated catheter.

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell in view of Gillick et al (6,599,296).

Gaskell discloses the claimed invention as discussed above. However, Gaskell does not teach the proximate end of the catheter being attached to or integrated with a stock base and father comprises a stock handle slidingly engaged to the stock base, wherein a mechanical interlink is conjoined to the stock handle such that upon sliding the stock handle in the stock base, the retractable device is moved.

Gillick et al discloses a ratcheting handle for intraluminal catheter systems that teaches the proximate end of a catheter (see figure 1) being attached to or integrated with a stock base (22) and father comprises a stock handle slidingly engaged to the stock base (32), wherein a mechanical interlink is conjoined to the stock handle such that upon sliding the stock handle in the stock base, the retractable device is moved (column 5 lines 57-67-column 6, lines 1-29).

It would have been obvious to one of ordinary skill in the art to modify the catheter of Gaskell by utilizing a sliding handle mechanism as taught by Gillick to actuate the retraction of the retractable device of Gaskell.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell in view of Arai et al (6,290,677).

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Gaskell discloses the claimed invention as discussed above. However, Gaskell does not teach a liquid injection port disposed on the catheter such that liquid may be injected into the catheter and extruded out said distal end of the catheter.

Arai teaches a liquid injection port (1) that can be connected to a catheter (see abstract, line 7) on the catheter such that liquid may be injected into the catheter and extruded out said distal end of the catheter (see abstract) through the slits (3) of Gaskell's catheter in order to inject a medicinal liquid into a specific site in the body of a patient.

7. Claims 5 and 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell in view of Dormia (4,347,846).

Gaskell discloses the claimed invention as discussed above. However, Gaskell does not teach the retractable device being a retractable basket comprising at least one flexible support wire.

Dormia teaches teach a retractable device being a retractable basket (see abstract) comprising at least one flexible support wire (see figure 1) for the purpose of removing foreign bodies from a patient.

It would have been obvious to one of ordinary skill in the art to modify the device of Gaskell and utilize the flexible wire basket disclosed in Dormia as the retractable device instead of the soft swab taught by Gaskell.

With regards to claim 6, Gaskell fails to disclose the retractable device comprising at least three flexible support wires conjoined or integrated together at a distal-apex.

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Dormia teaches the use of at least three flexible support wires (see figure 1) conjoined at a distal apex (6) as a retractable device in order to effectively trap foreign bodies retrieved from inside of a patient.

It would have been obvious to one of ordinary skill in the art to modify Gaskell and use three flexible support wires as the retractable member in order to effectively trap foreign bodies retrieved from inside of a patient.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell and Dormia and further in view of Zalucki (3,800,781).

Gaskell and Dormia disclose the claimed invention as discussed above.

However, Gaskell and Dormia do not teach a liquid impermeable barrier covering a portion of the retractable device.

Zalucki discloses a liquid impermeable barrier covering a portion of the retractable device (12), which provides a means for placing an identification label on the retractable catheter device (column 1, lines 64-67).

It would have been obvious to one of ordinary skill in the art to modify Gaskell and Dormia and incorporate a liquid impermeable cover as taught by Zalucki.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell in view of Oslund et al (6,793,648).

Gaskell discloses the claimed invention as discussed earlier. However, Gaskell does not disclose the use of a retractable net comprising at least one flexible support wire as the retractable device.

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Oslund et al teaches the use of a retractable net (32) comprising at least one flexible support wire (26) as a retractable device, in order to remove debris during the performance of a medical procedure (column 2, lines 26-28).

It would have been obvious to one of ordinary skill in the art to modify Gaskell and utilize a net as taught by Oslund as the retractable device in order to remove debris during the performance of a medical procedure.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell and Oslund and further in view of Zalucki.

Gaskell and Oslund disclose the claimed invention as discussed above.

However, Gaskell and Oslund do not teach a liquid impermeable barrier covering a portion of the retractable device.

Zalucki discloses a liquid impermeable barrier covering a portion of the retractable device (12), which provides a means for placing an identification label on the retractable catheter device (column 1, lines 64-67).

It would have been obvious to one of ordinary skill in the art to modify Gaskell and Oslund and incorporate a liquid impermeable cover as taught by Zalucki.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell and Oslund and further in view of Pevoto (6,702,759).

Gaskell and Oslund disclose the claimed invention as discussed above.

However, Gaskell and Oslund do not teach a squeezable material disposed within a retractable net.

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Pevoto teaches the use of a squeezable material (14) disposed within a retractable net (16) for the purpose of allowing the squeezable material to retain its perform shape when exposed to fluids (column 2, lines 43-50).

It would have been obvious to modify the device of Gaskell and Oslund by incorporating the squeezable material disposed within a retractable net as taught by Pevoto in order to allow the squeezable material to retain its perform shape when exposed to fluids.

12. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell in view of Naimark et al (US 2003/0073979).

Gaskell discloses the claimed invention as discussed above. However, Gaskell does not teach the use of a retractable tripod with a mesh attached to it.

Naimark et al teaches the use of a retractable tripod comprising at least three flexible support members (figure 4b) for the purpose of attaching a patch to the end of the flexible support members.

Naimark does not teach attaching a mesh to the end of the tripod. However, Naimark does teach attaching a patch to the end of the tripod. It would have been obvious to one of ordinary skill in the art to attach a mesh material to the end of the tripod instead of a patch since Naimark teaches using the end of the tripod for attachment.

With regards to claim 12, Naimark discloses the tripod structure (see figure 4b)
has a basket-like configuration. A basket is defined as a receptacle (Merriam-Webster's
Collegiate Dictionary Tenth Edition). A receptacle is defined as something that receives

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and contains something (Merriam-Webster's Collegiate Dictionary Tenth Edition).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Gaskell and include a tripod basket configuration as disclosed by Naimark with the squeezable material of Gaskell disposed within the tripod basket since the basket by definition is defined as something that receives and contains something.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gaskell and Naimark and further in view of Zalucki.

Gaskell and Naimark disclose the claimed invention as discussed above.

However, they do not teach the use of a liquid impermeable barrier covering at least a portion thereof.

Zalucki discloses a liquid impermeable barrier covering a portion of the retractable device (12), which provides a means for placing an identification label on the retractable catheter device (column 1, lines 64-67).

It would have been obvious to one of ordinary skill in the art to modify Gaskell and Naimark and incorporate a liquid impermeable cover as taught by Zalucki.

14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach in view of Wilson (4,730,949).

Wallach discloses the claimed invention as discussed earlier. However, Wallach does not teach the use of bristles configured in an arcuate manner.

Wilson teaches the use of arcuate shaped bristles in a surgical scrub brush used to antiseptically cleanse a patient in the area to be operated on, with the arcuate shape

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of the bristles providing the advantage of permitting and facilitating cleansing of areas that are otherwise difficult to reach with a standard brush.

It would have been obvious to one of ordinary skill in the art to modify the bristles in Wallach and utilize arcuate shaped bristles in order to permit and facilitate cleansing of areas that are otherwise difficult to reach with a standard brush.

15. Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al (US2002/0082552) in view of Gaskell (4,023,559).

Ding et al teaches treating an area of need of a patient by placing a drug onto a squeezable material and then applying the drug to an area of need (see paragraph 0001).

However, Ding et al does not teach the use of a cannulated catheter comprising an elongated portion, said elongated portion comprising a proximate end and a distal end, with a retractable device that is extended and retracted out the distal end of the catheter and a squeezable material disposed within the retractable device.

Gaskell teaches the use of such a retractable device for the purpose of enabling the squeezable material to reach a hard to reach area of the body.

It would have been obvious to one of ordinary skill in the art to combine Ding with the teachings of Gaskell and utilize a retractable device as taught by Gaskell to apply the sponge and drug as taught by Ding to a hard to reach area of the body.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al in view of Gaskell and further in view of Spillert et al (US 2003/0129183).

Ding and Gaskell disclose the claimed invention as discussed above. However, the do not teach the use of a cautery agent.

Spillert et al teaches the use of a cautery agent in a medical device to be applied to a patient for the purpose of modulating the clotting rate of blood in order to diagnose coagulopathies (paragraph 0004).

It would have been obvious to one of ordinary skill in the art to modify Ding and Gaskell and use a cautery agent as taught by Spillert as the drug applied to the squeezable material of Ding since Ding states that a drug for therapeutic purposes is to be applied to the sponge for delivery to an area of need and Spillert teaches that a cautery agent is a drug for therapeutic purposes that is to be applied to an area of need.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chu (US 2004/0236186) discloses an expandable surgical retractor. Korteweg (4,952,204) discloses a dry handle swab assembly and unit. Conn et al (4,424,054) discloses a fluid-expansible contraceptive tampon and applicator. Gellman (6,695,834) discloses an apparatus and method for stone removal from the body. Aiba et al (6,221,096) discloses an intravascular stent. Lederman (US 2003/0032936) discloses a catheter and method for its use. Harautuneian (3,592,192) discloses an intravenous catheter apparatus with catheter telescoped on outside of puncturing cannula. Forman et al (6,692,458) discloses an intra-pericardial drug delivery device with multiple balloons.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sundeep S Virdi whose telephone number is 571-272-4969. The examiner can normally be reached on M-F 9am-5:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sundeep Virdi Art Unit 3763

MICHAEL J. HAYES PRIMARY EXAMINER